

REMARKS

Claims 11, 12 and 22-33 are pending in the present application. Claims 25, 26 and 28-33 are withdrawn.

Claim 11, 12, 22-24 and 27 were rejected under 35 U.S.C. § 112, 1st paragraph because the scope of the claims is broader than the scope of the disclosure.

Claims 11 and 27 have now been amended. No new matter has been added. Reconsideration of the application based on the following remarks is respectfully requested.

Rejection Under 35 U.S.C. § 112, 1st Paragraph

Claim 11, 12, 22-24 and 27 were rejected under 35 U.S.C. § 112, 1st paragraph because the scope of the claims is broader than the scope of the disclosure. The Office stated that the amended claims encompass two processes, examples 4 and 5, both of which use cyclohexane as the cyclic hydrocarbon solvent and diisopropyl ether to isolate amorphous material.

Independent claim 11 of the present application has now been amended so as to recite a process for the preparation of amorphous atorvastatin calcium comprising:

“b) addition of cyclic hydrocarbon solvent selected from the group consisting of cyclohexane and methyl cyclohexane to provide a mixture of organic solvents;” and
“d) isolation of amorphous atorvastatin calcium from an organic phase comprising the mixture of organic solvents wherein the isolation comprises adding to said organic phase a solvent in which atorvastatin calcium is not soluble or is poorly soluble to obtain a precipitate containing atorvastatin which is in amorphous form.”

Support for the amendment can be found in the Specification as filed, for example, on page 9, third full paragraph: “Subsequently, a 0.4fold to a 0.8 fold volume of solvent with regard to the existing volume of solution, preferably, a 0.4fold volume of solvent, in which atorvastatin

calcium is not soluble, or is low soluble, is optionally added” and “[i]n this step a precipitate of final product – amorphous atorvastatin calcium salt is formed.”

The Applicants respectfully submit that feature b) of claim 1 is currently limited to a cyclic hydrocarbon solvent selected from the group consisting of cyclohexane and methyl cyclohexane to provide a mixture of organic solvents. Cyclohexane and methyl cyclohexane are closely related solvents. The exemplification of cyclohexane in examples 4 and 5 therefore also provides adequate support for methyl cyclohexane. The isolation step d) of claim 11 has now been amended to specify that the isolation comprises adding to the organic phase a solvent in which atorvastatin calcium is not soluble or is poorly soluble to obtain a precipitate containing atorvastatin which is in amorphous form. Diisopropyl ether is one solvent in which atorvastatin is not soluble or is poorly soluble which can be added to the organic phase in the isolation step. Applicants submit that the scope of claim 11 is therefore limited to the scope of the disclosure. Claims 12, 22-24 and 27, by virtue of their dependence on claim 11, are also so limited.

Withdrawal of the rejection to claims 11, 12, 22-24 and 27 under 35 U.S.C. § 112, 1st paragraph is respectfully requested.

CONCLUSION

The Commissioner is hereby authorized to charge any unpaid fees deemed required in connection with this submission, including any additional filing or application processing fees required under 37 C.F.R. §1.16 or 1.17, or to credit any overpayment, to Deposit Account No. 04-0100.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Dated: November 4, 2009

Respectfully submitted,

By N. B. Thot
Norman B. Thot
Registration No.: 47,993
DARBY & DARBY P.C.
P.O. Box 770
Church Street Station
New York, New York 10008-0770
(212) 527-7700
(212) 527-7701 (Fax)
Attorneys/Agents For Applicant